



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,053	04/06/2000	James W. Williams	29666/35415	1413

7590 07/30/2009  
Marshall O'Toole Gerstein  
Murray & Borun  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, IL 60606-6402

EXAMINER
----------

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
----------	--------------

1617

MAIL DATE	DELIVERY MODE
-----------	---------------

07/30/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

*Ex parte* JAMES W. WILLIAMS, ANITA CHONG,  
and W. JAMES WALDMAN

Appeal 2009-000280  
Application 09/529,053  
Technology Center 1600

Oral Hearing Held: Wednesday, July 8, 2009

Before DEMETRA J. MILLS, ERIC GRIMES and RICHARD M. LEOVITZ, *Administrative Patent Judges.*

ON BEHALF OF THE APPELLANTS:

LI SIEN, ESQ.  
Marshall, O'Toole, Gerstein, Murray & Borun  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606-6402

The above-entitled matter came on for hearing on Wednesday, July 8, 2009, commencing at 1:02 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, 9th Floor, Hearing Room A, Alexandria, Virginia, before Laurie B. Allen, Notary Public.

1 JUDGE MILLS: Just to let you know, we are familiar with the facts  
2 of your invention and the issues of the case. And you have 20 minutes you  
3 can spend however you like, but it would be most helpful to us if you would  
4 focus on your best argument, what you consider to be the critical issues.  
5 Thank you.

6 MS. HSIEN: Okay. Good. I take it the Examiner is not appearing?

7 JUDGE MILLS: No.

8 MS. HSIEN: Okay. Well, really, there are two main issues. The first  
9 one is whether the claims that recite combinations of the Leflunomide  
10 product, which for purposes of this appeal we are assuming have antiviral  
11 activity, and that was known in the art. A combination of a Leflunomide  
12 product with a pyrimidine compound that supplies cytidine, uridine or  
13 thymidine, so it enhances serum levels. It has to be significant enough to do  
14 that of these natural, occurring, pyrimidine nucleotides where that  
15 combination is not obvious. And, so that's one issue.

16 The second issue is whether a claim that recites combining  
17 Leflunomide product with pyrimidines that don't have antiviral activity is  
18 new matter. The Examiner has acknowledged that that is not obvious, but  
19 thinks that it adds new matter. So, we're hoping that one or the other, or  
20 maybe both of these claims, are going to be allowable.

21 With respect to the first claim, the enhancing serum levels as cited in  
22 uridine and thymidine, the Examiner has supplied a couple of prior art  
23 references that refer to unnatural nucleotide analogs that are used to treat  
24 AIDS. The problem is that when you combine the Leflunomide product  
25 with these pyrimidines that are unnatural and have antiviral activity, even  
26 that accommodation doesn't get you to the claim language, because the claim

1 language by its nature excludes the unnatural analogs because they don't  
2 supply serum levels of uridine, cytidine or thymidine.

3 And, the Examiner, we pressed him for proof of his proposition,  
4 which was that these antiviral agents do supply natural pyrimidine  
5 nucleotides, and he didn't provide any. In contrast, we did have some  
6 evidence and our Atwood Declaration, which is page B3 of the appendix.  
7 So paragraph 8 of Atwood Declaration, this is an expert in the field, and he's  
8 providing us evidence as to what one of ordinary skill in the art would  
9 understand. He says that "The definition of pyrimidine compounds confirms  
10 that the contemplative pyrimidine compounds would not have antiviral  
11 activity."

12 And then in paragraph 10, item B, it says "The definition of  
13 pyrimidine compound excludes pyrimidine compounds with antiviral  
14 activity." So I think that we have actually provided evidence that analogs,  
15 which are administered for the purpose of being incorporated into DNA and  
16 messing up RNA synthesis of viruses couldn't possibly meet the limitation  
17 of our claims.

18 JUDGE GRIMES: The statements in the declaration don't specifically  
19 say that the pyrimidine analogs that are in the prior art wouldn't be  
20 metabolized into naturally occurring pyrimidines. Do they? I mean, does  
21 the declaration say that?

22 MS. HSIEN: The declaration doesn't say that in so many words, but it  
23 does say.

24 JUDGE GRIMES: It says that "Naturally occurring pyrimidines  
25 would not have antiviral activity."

26 MS. HSIEN: Yes.

1 JUDGE GRIMES: Not that pyrimidines with antiviral activity could  
2 not provide some naturally occurring pyrimidines. Right? Isn't it the  
3 Examiner's position that the pyrimidine analogs that are in the prior art  
4 would be expected to provide intermediates to pyrimidine synthesis because  
5 they have a pyrimidine?

6 MS. HSIEN: I think that is the Examiner's position. I think he is  
7 reading the claim to say "pyrimidine compound." I don't think he's  
8 necessarily reading the claim to say pyrimidine compound that supplies  
9 increased serum levels of uridine, cytidine and thymidine. And, you know,  
10 he is entitled to read it broadly, but he is not entitled to read it to encompass  
11 something that can't possibly be true.

12 He did provide evidence that when you give AIDS drugs, they  
13 actually do interfere with DNA synthesis and you get toxic effects, and that  
14 they do not supply naturally occurring pyrimidine nucleotides. And I think  
15 that when you challenge the Examiner on a fact they do have an obligation  
16 to come back with evidence that supports their theory. Simply because it's a  
17 speculative idea that it might be true, doesn't mean that in fact it is true. And  
18 when we provided evidence that suggests otherwise, I think he does have an  
19 obligation to provide some definite evidence.

20 JUDGE LEBOVITZ: What evidence suggests otherwise?

21 MS. HSIEN: I think you can infer from the Atwood Declaration,  
22 although you're right. It doesn't say so in so many words. You can infer that  
23 analogs, which do have an antiviral effect, do not supply uridine, cytidine  
24 and thymidine. It levels sufficient increase serum levels of those  
25 nucleotides.

26

1           We also had other evidence showing that people who are given these  
2           analogues suffer from deficiencies in pyrimidine levels. It's B14 and it says  
3           that "AZT has cytotoxicity in human bone marrow progenitor cells."

4           JUDGE GRIMES: Which reference is that?

5           MS. HSIEN: It is Sommadossi et al.

6           JUDGE LEOVITZ: Where are you reading from?

7           MS. HSIEN: The Abstract: "We evaluated the effects of natural  
8           purine and pyrimidine nucleotides and protection from or reversal of AZT  
9           cytotoxicity." So, because these unnatural analogues don't supply or interrupt,  
10          rather, the pyrimidine pathways, they don't increase serum levels of uridine,  
11          cytidine or thymidine, and they would be expected to have no effect in  
12          helping the toxicity of Leflunomide product. So, in other words, our  
13          invention is that if we supply natural pyrimidines, we can reduce toxicity  
14          associated with Leflunomide.

15          JUDGE LEOVITZ: I'm sorry. Where were you reading from when  
16          you were reading about the AZT?

17          MS. HSIEN: Oh, it was page B.

18          JUDGE LEOVITZ: Of which reference?

19          MS. HSIEN: Sommadossi, B14. And with respect to the other issue  
20          in the case, which is whether there is new matter with respect to pyrimidines  
21          that don't have antiviral activity, I think we did provide declaratory evidence  
22          to that effect and there is case law saying that where there is an inherent  
23          property that must necessarily be an inherent property of the claimed device  
24          of the claimed method or the claimed composition that inherent property can  
25          be added into the claims. And I think we've shown with the declaratory  
26

1 evidence that in fact compounds that supply natural pyrimidines don't have  
2 antiviral effect.

3 I'd also like to point you to a passage in the application that supports  
4 the idea that there are pyrimidines that do and pyrimidines that don't have  
5 antiviral activity. And that would be page 17 of the specification, line 17.

6 JUDGE GRIMES: I'm sorry. That's evidence of what?

7 MS. HSIEN: Oh, well, to the extent that the invention says that you  
8 can combine Leflunomide product with antiviral agents, and among these  
9 antiviral agents are some of the very unnatural analogs that the Examiner has  
10 cited in the prior art. And it lists, for example, at line 21 of page 17. It says,  
11 "Zidovudine, didanosine, or zalcitabine." Those were analogs that were  
12 described in the Hammer reference. So the extent that we described the  
13 genus of pyrimidines, some of which have antiviral activity and some of  
14 which don't, we are permitted to carve out with a negative limitation the  
15 types of pyrimidines that do have antiviral activity.

16 So I think that claim 46 that recites "administering a pyrimidine  
17 compound without antiviral activity" is properly entered as not new matter  
18 for either one of those reasons. One is because it describes an inherent  
19 property of the pyrimidine compounds that we contemplated using, or  
20 because it describes a subspecies of pyrimidine compounds that we were  
21 permitted to carve out of the application as a negative limitation.

22 JUDGE MILLS: So as we understand your overall argument is that  
23 the pyrimidine analogs in the prior art do not function to enhance their own  
24 levels of uridine, cytidine and thymidine?

25 MS. HSIEN: Yes, that's correct. Yes. Thank you.

26

1 JUDGE MILLS: I don't believe we have any other questions for you.

2 MS. HSIEN: Thank you.

3 (Whereupon, at 1:20 p.m., the proceedings were concluded.)

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26